MAY 0 2 2014
K140272

5. 510(k) Summary

Submitter:	St. Jude Medical 6901 Preston Road, Plano, TX 75024 **Establishment Registration Number: 1627487**
Contact Person:	Diana Ortega Regulatory Affairs Specialist Phone (972) 526 8225 Fax (972) 526 8325
Date Prepared:	January 30, 2014
Trade Name:	Swift-Lock™ Anchor
Classification Name:	Stimulator, Spinal Cord, Implanted (Pain Relief) GZB
Classification:	Class II – 21 CFR 882.5880
Product Code:	GZB

5.1 Predicate Device:

The subject device is substantially equivalent to the Swift-Lock™ Anchor (K092371) cleared on December 23, 2009

5.2 Device Description:

The Swift-Lock™ Anchor is a single-use device used to attach the implanted lead to the fascia or interspinous/supraspinous ligament via suturing. The anchor is made up of male and female components that are partially over-molded with silicone rubber and joined by a stainless steel pin. The Swift-Lock™ Anchor has a mechanical mechanism to secure the lead body to the anchor. This is accomplished by a rotating midsection where the male and female components align and lock into place. When properly executed, the anchor securely holds the lead into place enhancing the lead to anchor holding force. The Swift-Lock™ Anchor has several visual and tactile features such as; raised eyelets, indicating arrows, and a 1 cm depth indicator that aid the physician in inserting the anchor and securing the anchor to the lead. The Swift-Lock™ Anchor also has strain relief cuts in the distal end column for improved strain relief and increased flexibility and a thinner tapered distal tip for ease of insertion.

5.3 Indications for Use:

SJM Neurostimulation Systems are indicated for spinal cord stimulation (SCS) in the management of chronic pain of the trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.

The Swift-Lock™ anchor is intended to be an accessory to the leads component of the spinal cord stimulation (SCS) system, functioning to secure compatible St. Jude Medical™ (SJM) leads to the fascia or interspinous/supraspinous ligament.

5.4 Summary of Technological Characteristics of the New Device Compared to the Predicate Device:

The Swift-Lock™ Anchor has the same intended use and indications for use as the predicate device. The Swift-Lock™ Anchor functions in the same manner as the predicate device in that it is used to secure SCS leads into place during implantation. The mechanism by which this happens is the same. The anchor slides over an SCS lead and is secured to the fascia or interspinous/supraspinous ligament via suturing. This function is the same for the predicate device. The Swift-Lock™ Anchor has the same operating principle as the predicate device in that after the device is slid into place along the SCS lead, the anchor is then turned and locked into position using the same mechanical principle of "gripping" the lead to the anchor.

The predicate device and the subject device have the same interlocking core components designed as male and female parts joined together by a stainless steel pin. The interlocking core components incorporate a plastic material formulation called PEEK. The indicating arrows are laser engraved on the male and female parts and the core is also molded with suture grooves for extra suturing purposes if desired. These two interlocking core components are partially over molded with Silicone/$BaSO_4$ sleeves in order to provide distal strain relief.

The Swift-Lock™ Anchor is comprised of identical materials and is processed by identical manufacturing methods as the predicate device cleared under K092371. The predicate device and the subject device are both single use devices, have the same cylindrical shape and have the same base material for the outer sleeve which is a formulation of Silicone with Barium sulfate.

All other technological characteristics of the Swift-Lock™ Anchor were not affected by the modifications to the predicate device including, Sterilization, EtO Residuals, Packaging, Shelf Life, and Biocompatibility. Where differences exist between the subject device and the predicate device design and labeling, performance testing and labeling review demonstrated that these differences do not adversely affect the safety and effectiveness of the subject device.

5.5 Non-Clinical Test Summary:

Completion of all verification and validation activities demonstrated that the subject device meets the predetermined design and performance specifications. The testing included mechanical testing to confirm that the minor differences in the design do not adversely affect the safety and effectiveness of the subject device.

5.6 Conclusion:

St. Jude Medical considers the Swift-Lock™ Anchor to be substantially equivalent to the predicate device listed above. This conclusion is based upon the device similarities in design, technological characteristics, principle of operation, indications for use and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 2, 2014

St. Jude Medical
Diana Ortega
Regulatory Affairs Specialist
6901 Preston Road
Plano, TX, 75024

Re: K140272
Trade/Device Name: Swift-Lock™ Anchor (model 1192)
Regulation Number: 21 CFR 882.5880
Regulation Name: Stimulator, Spinal Cord, Implanted (Pain Relief)
Regulatory Class: Class II
Product Code: GZB
Dated: January 31, 2014
Received: February 3, 2014

Dear Ms. Ortega:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Peña -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140272

Device Name
Swift-Lock™ Anchor

Indications for Use *(Describe)*
SJM Neurostimulation Systems are indicated for spinal cord stimulation (SCS) in the management of chronic pain of the trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.
The Swift-Lock™ Anchor is intended to be an accessory to the leads component of the spinal cord stimulation (SCS) system, functioning to secure compatible St. Jude Medical™ (SJM) leads to the fascia or interspinous/supraspinous ligament.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos E. Rena -S

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